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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.        | CONFIRMATION NO.       |
|---|-------------|----------------------|----------------------------|------------------------|
| 10/596,934  | 05/31/2007  | Paul R. Roberts      | 040857/313663              | 2531                   |
| 826 7590 06/27/2008<br>ALSTON & BIRD LLP<br>BANK OF AMERICA PLAZA<br>101 SOUTH TRYON STREET, SUITE 4000<br>CHARLOTTE, NC 28280-4000 |             |                      | EXAMINER<br>LLOYD, EMILY M |                        |
|   |             |                      | ART UNIT<br>3736           | PAPER NUMBER           |
|   |             |                      | MAIL DATE<br>06/27/2008    | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/596,934

**Applicant(s)**

ROBERTS, PAUL R.

**Examiner**

EMILY M. LLOYD

**Art Unit**

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-19 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-19 and 21-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This office action is in response to the amendment filed 21 February 2008. The Examiner acknowledges Applicant's amendments to claims 11-19 and 21-28 and the cancellation of claim 20; as well as Applicant's amendments to the specification and replacement sheets for Figures 1-3. Currently, claims 11-19 and 21-28 are pending.

#### ***Inventorship***

2. In view of the papers filed 21 February 2008, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the addition of inventor Jonathan Mark Featherstone.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Further, the Statement of Lack of Deceptive Intent under 37 CFR 1.48(a) signed by Jonathan Mark Featherstone cites 37 CFR 1.48(a), while the Assent of Assignee to Correction and/or Addition to Originally Named Inventor(s) 37 CFR 1.48(c)(5) cites 37 CFR 1.48(c). As the requirements for 37 CFR 1.48(a) are met but the requirements for 37 CFR 1.48(c) have not been met, Jonathan Mark Featherstone was added as an inventor under 37 CFR 1.48(a).

***Claim Objections***

3. Claim 12 is objected to because of the following informalities: claim 12 should start with "The" instead of "An". Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 11 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by United States Patent 6931276 (Streng et al.).

Regarding claim 11, Streng et al. disclose an apparatus for detecting the location of electrical activity in the all of a human bladder, comprising: a detector (elongated threadlike electrode 10 Figure 1) adapted to be introduced into the bladder via the urethra (Column 3 lines 32-35), and having a connector to the exterior (wire 13 Figure 1 and Column 3 lines 41-16); and a filling lumen (channel of tube 20 Figure 1) adapted to permit passage of a sterile fluid from the exterior through an open end of the filling lumen into the bladder for distending the bladder (Column 3 lines 35-41).

Regarding claim 21, Streng et al. disclose the apparatus according to claim 11 and comprising multiple lumens (parallel channels 22 and 24, Figures 3 and 4).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 12-19 and 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Streng et al. as modified by United States Patent 5662108 (Budd et al.).

Regarding claim 12, Streng et al. discloses the apparatus according to claim 11. Streng et al. do not disclose that the detector comprises an expandable device adapted for passage through the urethra in a collapsed condition and reversibly expandable when in the bladder. Budd et al. teach a detector that comprises an expandable device (inflatable balloon 96 Figure 3; basket catheter 80 Figure 4) adapted for passage through the urethra in a collapsed condition and reversibly expandable when in the bladder (Column 8 lines 64-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such an expandable device adapted for passage through the urethra in a collapsed condition and reversibly expandable when in the bladder as taught by Budd et al. in the invention of Streng et al. as this would enable multiple portions of the bladder to be measured at the same time.

Regarding claim 13, Streng et al. as modified by Budd et al. disclose the apparatus according to claim 12 wherein said expandable device has a plurality of detection sites thereon (Budd et al. "array or set of passive electrodes 48 typified by passive electrode 72" Column 5 lines 3-4 and Figure 3; "multiple passive electrode sites typified by electrode 84" Column 5 lines 23-24 and Figure 4).

Regarding claim 14, Streng et al. as modified by Budd et al. disclose the apparatus according to claim 13 wherein said detection sites are uniformly distributed on the surface thereof (Budd et al. Figure 4).

Regarding claim 15, Streng et al. as modified by Budd et al. disclose the apparatus according to claim 14. Streng et al. as modified by Budd et al. do not disclose expressly that the expandable device resembles a sphere in the expanded

state. Instead, Streng et al. as modified by Budd et al. discloses the expandable device resembles an oblate shape (Budd et al. inflatable balloon 96 Figure 3).

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to shape the expandable device of Streng et al. as modified by Budd et al. into a spherical shape because Applicant has not disclosed that shaping the expandable device into a sphere provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Streng et al. as modified by Budd et al.'s expandable device, and Applicant's invention, to perform equally well with either the shape taught by Streng et al. as modified by Budd et al. or the claimed spherical shape because both shapes would perform the same function of providing a plurality of detection sites equally well considering the typical size of human anatomy.

Therefore, it would have been prima facie obvious to modify Streng et al. as modified by Budd et al. to obtain the invention as specified in claim 15 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Streng et al. as modified by Budd et al.

Regarding claim 16, Streng et al. as modified by Budd et al. disclose the apparatus according to claim 14 wherein said expandable device comprises a cage (Budd et al. basket catheter 80 Figure 4) having a plurality of arcuate arms (Budd et al. limb 82 Figure 4) extending between opposite poles (Budd et al. proximal and distal ends of central shaft 86 Figure 4).

Regarding claim 17, Streng et al. as modified by Budd et al. disclose the apparatus according to claim 12 and including an external telescopic connector whereby relative telescoping movement causes the device to expand and contract on demand (Budd et al. Column 8 lines 64-67; the device inherently can contract as it is also removable from the body).

Regarding claim 18, Streng et al. as modified by Budd et al. disclose the apparatus according to claim 12 and comprising an inflatable device (Budd et al. inflatable balloon 96 Figure 3).

Regarding claim 19, Streng et al. as modified by Budd et al. teach the apparatus according to claim 18 wherein said device includes an inflation lumen (Streng et al. channel 22 Figure 3, Budd et al. balloon catheter 94 Figure 3) having an external closure (Streng et al. the channel 22 inherently has an external closure to keep the fluid in the bladder from flowing backwards in channel 22 and from flowing out of channel 24 before the testing is complete, Figure 2, also Figure 6; Budd et al. the lumen inherently has a closure to keep the material inflating the balloon 96 Figure 3 inside of the balloon; it would have been obvious to have this closure externally for easy physician control to allow the balloon to deflate easily).

Regarding claim 22, Streng et al. as modified by Budd et al. disclose the apparatus according to claim 11 and comprising an array of detection sites adapted to detect electrical activity in the wall of the bladder whereby the location of said electrical activity can be determined (Budd et al. Column 9 lines 18-27).



Regarding claim 23, Streng et al. as modified by Budd et al. disclose the apparatus according to claim 22 wherein said detection sites are uniformly distributed (Budd et al. Figure 4).

Regarding claim 24, Streng et al. as modified by Budd et al. disclose the apparatus according to claim 12 and further comprising orientation means whereby the orientation of an expandable device in the bladder may be determined from outside the bladder (Budd et al. Column 11 line 44 – Column 12 line 7).

Regarding claim 25, Streng et al. as modified by Budd et al. disclose the apparatus according to claim 12 and further including a lumen adapted to receive a stiff curved guide member for steering of the expandable device (Streng et al. channels 22 and 24 Figure 3; also Budd et al. a catheter such as balloon catheter 94 inherently has a lumen; any lumen can receive a stiff curved guide member for steering it and such devices are well known in the art).

Regarding claim 26, Streng et al. as modified by Budd et al. disclose the apparatus according to claim 11 and further including an ablation tool (Budd et al. therapy catheter 18 Figure 3) adapted for insertion through the urethra and operable to ablate (Budd et al. delivery electrode 60 Figure 3 and Column 5 lines 17-18) the internal surface of the bladder wall.

Regarding claim 27, Streng et al. as modified by Budd et al. disclose the apparatus according to claim 26 wherein the tip of said tool (Budd et al. delivery electrode 60 Figure 16) is detectable by a position sensing apparatus (Budd et al. locator electrode 68 Figure 16).

Regarding claim 28, Streng et al. as modified by Budd et al. disclose the apparatus according to claim 27 wherein the tip of said tool is adapted to be electrically active (Budd et al. delivery electrode 60 Figure 3) and wherein said apparatus is adapted to detect said activity (Budd et al. Column 4 lines 42-50).

***Response to Arguments***

10. Applicant's arguments with respect to claims 11-19 and 21-28 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LLOYD whose telephone number is (571)272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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